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10/716,417	11/20/2003	Takeo Tanaami	032106	6545

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EXAMINER	
BOWERS, NATHAN ANDREW	
ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/716,417	TANAAMI ET AL.	
	Examiner	Art Unit	
	Nathan A. Bowers	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1) Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christian (US 4708931) in view of Schembri (US 20040087033) and either Schnipelsky (US 6645758) or Applicant's admitted prior art.

With respect to claims 1 and 2, Christian discloses a biochip cartridge comprising a tabular substrate member (Figure 13:121). A flexible cover (Figure 13:150) is airtightly attached to the surface of the substrate member. The substrate includes an area (Figure 12:122) for detecting desired biopolymers. Christian additionally discloses additional areas (Figure 12:125 and Figure 12:124 and Figure 12:123) that are fully capable of storing biopolymers and preprocessing biopolymers. Christian additionally discloses that flow paths (Figure 12:133 and Figure 12:132 and Figure 12:131) for connecting these areas are formed in the substrate member. This is taught in column 12, line 15 to column 13, line 5. However, Christian does not expressly indicate that the biopolymers and biopolymer solutions are transferred sequentially from a storage area to a preprocessing area to a detection area to a waste reservoir in a time-differentiated manner. Christian does not expressly disclose that the substrate is formed using an elastic material.

Schembri discloses an elastic substrate (Figure 4:334). A plurality of channels and chambers (Figure 4:340) are formed in the substrate. The substrate is capable of accommodating an area (Figure 4:332) for detecting desired biopolymers. This is disclosed in paragraphs [0087]-[0091].

Schnipelsky discloses a biochip cartridge comprising a film substrate member (Figure 2:12) formed using an elastic material, and a flexible cover (Figure 2:14) attached to the surface of the substrate in an airtight manner. This is disclosed in column 9, lines 33-49 and column 10, lines 45-53. An area (Figure 1:32) for storing/collecting biopolymers, an area for preprocessing biopolymers (Figure 1:26) and an area (Figure 1:40) for detecting desired biopolymers are all formed on the substrate, so that the biopolymers can be successively moved from the storage area to the detection area through gaps (Figure 1:21, 43, 44, 48, 49, 50, 52) serving as flow paths. Schnipelsky also incorporates a waste area (Figure 1:42). This is disclosed in column 9, line 50 to column 10, line 15.

Applicant discloses that it is known in the art to prepare biochip cartridges comprising a tabular substrate member attached to a flexible cover in an airtight manner. The use of fluidly connected storage (Figure 5:43), preprocessing (Figure 5:44) and detection (Figure 5:45) areas is also known. This is taught on pages 3 and 4 of the specification. Applicant further discloses on page on page 4 of the specification that it is well known in the art to use a waste liquid reservoir (Figure 5:47) for storing drainage from the detection area.

Christian, Schembri, Schnipelsky, and the admitted prior art are analogous art because they are from the same field of endeavor regarding detection of analytes using biochemical arrays.

At the time of the invention, it would have been obvious to create the tabular substrate disclosed by Christian from an elastic material. In paragraph [0006], Schembri indicates that flexible substrates are known in the art to be advantageous over rigid substrates in a variety of ways. Flexible substrates are more convenient and less costly to handle during manufacturing. Furthermore, elastic substrates are beneficial because they can conform to the contour of a variety of support surfaces, and are less likely to break under impact.

At the time of the invention, it would have been obvious to alter the arrangement of channels and chambers in the apparatus disclosed by Christian in order to ensure that biopolymers and biopolymer solutions are transferred sequentially from a storage area to a preprocessing area to a detection area to a waste reservoir in a time-differentiated manner. This would have been beneficial because it would have guaranteed that biopolymers are adequately treated to promote increased detection before they are moved into the hybridization area. The admitted prior art in particular suggests that it is known to sequentially move biopolymers through storage and preprocessing areas before arrival at the detection area.

With respect to claims 3-5, 7 and 13, Christian, Schembri, and the admitted prior art/Schnipelsky disclose the apparatuses set forth in claims 1 and 2 wherein the biopolymers are transferred by pressing the cover with a roller-like rigid body (Figure 13:130), and squeezing each gap formed in the substrate member. This is disclosed by Christian in column 12, line 41 to column 13, line 5.

With respect to claim 6, Christian, Schembri, and the admitted prior art/Schnipelsky disclose the apparatus in claims 1 and 2 wherein a cover is attached to both the top and bottom surfaces of the substrate member. Figure 13 of Christian indicates that the bottom and top surfaces of the substrate are sealed by cover members 152 and 150, respectively.

With respect to claim 8, Christian, Schembri, and the admitted prior art/Schnipelsky disclose the apparatus in claim 6 wherein the covers are formed using plastics. In column 12, lines 64 and 65, Christian indicates that the covers are made from suitable flexible materials. In column 14, lines 39-54, Christian additionally indicates that the cover members 14' and 40' of a similar biochip cartridge are made from suitable plastic materials.

With respect to claim 9, Christian, Schembri, and the admitted prior art/Schnipelsky disclose the apparatus set forth in claim 6 as set forth in the 35 U.S.C. 103 rejection above. Schnipelsky additionally discloses in column 10, lines 45-53 and column 13, lines 35-45 that it is known in the art to provide covers that are is transparent to facilitate optical detection. Applicant's admitted prior art additionally teaches that transparent cover materials are well known.

With respect to claim 10, Christian, Schembri, and the admitted prior art/Schnipelsky disclose the apparatus set forth in claim 3 as set forth in the 35 U.S.C. 103 rejection above. In addition, Applicant's admitted prior art teaches on pages 4 and 5 that pockets (Figure 5:48, 50) for storing preprocessing solutions are formed in different positions so that when the substrate

member is squeezed, a preprocessing solution is released in a time differentiated manner. Schnipelsky teaches that a plurality of pockets (Figure 1:30, 34, 36, 38) are formed, and are emptied when pressed down upon by the roller.

With respect to claim 11, Christian, Schembri, and the admitted prior art/Schnipelsky disclose the apparatus set forth in claims 1 and 2 as set forth in the 35 U.S.C. 103 rejection above. Although the above references do not disclose that the substrate is formed into a wedge shape, this embodiment of the invention would not change the function of the device in an unexpected manner. In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was the recitation of relative dimensions that do not alter performance, the claimed device is not patentably distinct from the prior art. Accordingly, the claimed wedge shape is considered not to be patentably distinct from the substrate disclosed by Christian.

With respect to claim 12, Christian, Schembri, and the admitted prior art/Schnipelsky disclose the apparatus set forth in claim 3 as set forth in the 35 U.S.C. 103 rejection above. In addition, Applicant teaches on page 5 that the use of a valve for checking the flow of solutions is well known in the art. Applicant states that the valve opens when a solution flowing through the flow path is pressurized. Schnipelsky additional teaches in column 10, lines 6-14 and in column 13, line 53 to column 14, line 4 that it is known in the art to provide valves within various flow paths.

2) Claims 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christian (US 4708931) in view of Schembri (US 20040087033) and either Schnipelsky (US 6645758) or Applicant's admitted prior art as applied to claims 1 and 2, and further in view of Furcht (US 6303288).

With respect to claims 14-16, Christian, Schembri, and the admitted prior art/Schnipelsky disclose the apparatus set forth in the 35 U.S.C. 103 rejection above, however do not expressly disclose that the biochip cartridge is made separable into a first housing and a second housing that are detachably joined.

Furcht discloses a genetic testing system comprising a test strip (Figure 1:11) that includes a first housing (Figure 3:32) and a test card (Figure 1:14) comprising a second chamber (Figure 2:63, 65). Column 8, line 34 to column 9, line 45 indicates that the first and second housings are detachably coupled, so that nucleic acid biopolymers stored and processed in the first chamber are moved into the second chamber for detection. The second chamber comprises a joint (Figure 2:62) designed to facilitate attachment with the first chamber. In this way, biological samples can be added to the first housing and transferred to the second housing at different times. Column 11, lines 27-33 indicate that samples derived from the first chamber are amplified and detected in the second chamber through the use of PCR and hybridization to complementary biopolymer arrays.

Christian, Schembri, Applicant's admitted prior art, Schnipelsky, and Furcht are analogous art because they are from the same field of endeavor regarding the detection of biopolymers.

At the time of the invention, it would have been obvious to make the storage and detection areas of the apparatus disclosed by Christian, Schembri, and the prior art/Schnipelsky detachable. This would have been beneficial because it would have allowed one to prepare a biological sample in a storage chamber under conditions that are different than experienced by the detection chamber. The two chambers could be combined to complete analysis at any convenient time. Many biochemical preparation procedures involve chemicals, enzymes or abnormal conditions (fluctuating temperatures and pHs, lysis enzymes, etc.) that are necessary to get a sample ready for analysis, but would be detrimental to the analytical procedures themselves. Therefore, one would be able to operate the biochip cartridge in a much more flexible and efficient manner if first and second housings comprising storage and detection areas were detachably separable.

With respect to claims 17 and 18, Christian, Schembri, the admitted prior art/Schnipelsky, and Furcht disclose the apparatus set forth in claims 14 and 16. In addition, Christian teaches that it is common for substrates forming bioprocess chambers to be flexible. This is disclosed in column 12, line 15 to column 13, line 4 and in column 14, lines 39-54. Schnipelsky additionally discloses in column 10, lines 45-53 and column 13, lines 35-45 that it is known in the art to provide covers that are is transparent to facilitate optical detection. Applicant also teaches on page 3 of the specification that flexible and transparent materials are well known in the art.

3) Claims 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christian (US 4708931) in view of Schembri (US 20040087033) and Schnipelsky (US 6645758) or Applicant's admitted prior art as applied to claims 1 and 2, and further in view of McGarry (US 6642046).

With respect to claims 19 and 20, Christian, Schembri, and the admitted prior art/Schnipelsky disclose the apparatus set forth in claims 1 and 2 as set forth in the 35 U.S.C. 103 rejection above. Christian additionally indicates that biopolymer microarrays are mounted on a slide that is 0.127 mm wide and 0.761 mm long. Christian, however, does not expressly disclose that a carrier is a glass slide.

McGarry discloses a biochemical detection device in which biopolymer microarrays are mounted on a glass slide (Figure 2:20). The glass slide is mounted upon a substrate (Figure 1:32) in such a way that the microarrays located on the glass slide are opposite the surface (Figure 1:34) of the substrate. The glass slide and substrate form a reaction area (Figure 10:30) in which hybridization occurs. This is disclosed in column 5, line 51 to column 6, line 10. McGarry teaches in column 8, lines 23-39 that the dimensions of the glass slide are no greater than 25 mm wide by 75 mm long.

Christian, Schembri, Schnipelsky, Applicant's admitted prior art and McGarry are analogous art because they are from the same field of endeavor regarding biochemical detection devices.

At the time of the invention, it would have been obvious to fashion the microarray carrier disclosed by Christian from a glass slide. This is due to the fact that glass is a rigid and inert substrate that is capable of covalently bonding to biochemical probes. Glass is relatively

inexpensive and easily attained. The use of glass to accommodate the reactive surface of hybridization reaction chambers is well known in the art. Minimizing the size of the glass slide would also have been advantageous because it would have allowed one to reduce the volume of the hybridization detection area. This would have reduced the amount of sample needed to conduct the experiment, and would have reduced costs associated with the purchase of reagents.

With respect to claims 21, Christian, Schembri, the admitted prior art/Schnipelsky, and McGarry disclose the apparatus set forth in claim 19 as set forth in the 35 U.S.C. 103 rejection above. In addition, the prior art discloses that a collection area (Figure 5:43) for storing biological samples, a preprocessing solution storage area (Figure 5:44) for storing preprocessing solutions, a plurality of washing solution storage areas (Figure 5:48, 50), a combination/detection area (Figure 5:45) for performing hybridization reactions, and a waste liquid reservoir (Figure 5:47) are all provided for within the biochip cartridge. This is disclosed in column 9, line 33 to column 10, line 15. A flow path connecting all the areas and storages in series is provided.

With respect to claim 22, Christian, Schembri, the admitted prior art/Schnipelsky, and McGarry disclose the apparatus set forth in claim 19 as set forth in the 35 U.S.C. 103 rejection above. In addition, the prior art discloses that the biological samples are transferred by squeezing the substrate member with a rigid roller (Figure 6:41) in the direction from the collection area toward the combination area. This is disclosed on page 5 of Applicant's specification.

With respect to claims 23 and 24, Christian, Schembri, the admitted prior art/Schnipelsky, and McGarry disclose the apparatus set forth in claim 19 as set forth in the 35 U.S.C. 103 rejection above. Furthermore, McGarry teaches that the glass slide biopolymer microarray (Figure 1:20) is mounted on the substrate member (Figure 1:32) in such a manner that the array area of the glass slide is opposed to the combination area (Figure 6:30). Additionally, a cover (Figure 1:54) formed of rigid material is attached to the substrate so that a cavity is formed therebetween.

At the time of the invention, it would have been obvious to form the hybridization/combination area disclosed by Christian from a glass slide microarray supported by a rigid cover and positioned oppositely from the substrate. This would have been beneficial because it would have created a sturdy reaction chamber within which hybridization can be monitored. The rigid cover member would have been able to provide a backing to the glass slide microarray, upon which pressure could be transmitted to force the glass slide into an airtight seal with the substrate. The subsequently formed hybridization and combination area can be constructed to be microfluidic in size, which would decrease expenses associated with the purchase of reagents.

With respect to claim 25, Christian, Schembri, the admitted prior art/Schnipelsky, and McGarry disclose the apparatus set forth in claim 19 as set forth in the 35 U.S.C. 103 rejection above. In addition, the prior art teaches on pages 3 and 4 of Applicant's specification that DNA and RNA extraction mechanisms are well known, and are practiced during preprocessing operations.

Response to Arguments

All objections to the claims made in the previous Office Action (2/7/06) have been withdrawn in response to Applicant's amendments.

Applicant's arguments, see page 9, filed 01 June 2006, with respect to the rejections under 35 U.S.C. 102 involving Schnipelsky have been fully considered and are persuasive. The rejections of claims 1, 12(1) and 13/(1) under 35 U.S.C. 102 have been withdrawn.

Applicant's arguments, see pages 10-12, filed 01 June 2006, with respect to the rejection(s) of claim(s) 1-5, 7 and 10-13 under 35 U.S.C. 103 have been fully considered and are persuasive. Therefore, the rejections involving Schnipelsky/Applicant's admitted prior art in view of Hayes have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Christian in combination with Schembri and either Schnipelsky or Applicant's admitted prior art.

The Christian reference clearly discloses a tabular substrate airtightly sealed by a flexible cover. It is clear that the substrate includes a plurality of chambers and channels formed *in* the substrate. Deficiencies in Christian regarding substrate construction materials and the spatial arrangement of chambers are addressed by Schembri, Schnipelsky, and the admitted prior art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1226. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NAB

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